510(k) Summary May 7, 2012

1. Submitter Name and Address

Medicalgorithmics LLC	245 West 107th St., Suite 11A New York, NY 10025, USA
Contact Person	Martin Jasinski, phone (917) 9419581, fax (817) 5829527

2. Device

Trade name:	PocketECG v2 – Medicalgorithmics Unified Arrhythmia Diagnostic System
Classification name:	Arrhythmia Detector and Alarm
Product code:	DSI
Regulation no:	870.1025
Class:	Class II, Special Controls

3. Substantial Equivalence

The selected predicate devices are:

1. CardioNet's Ambulatory ECG Monitor, K072558 (Reg. no. 870.1025)
2. Universal Medical's Heartrak Smart AF, K071130, (Reg. No. 870.2920)
3. GE's SEER Light Extend Compact Digital Holter System, K050731 (Reg. no. 870.2800)

4. Device Description

PocketECG v2 – Medicalgorithmics Unified Arrhythmia Diagnostic System is an ambulatory ECG monitor which analyzes electrographic signal, classifies all detected heart beats and recognizes rhythm abnormalities. All detection results, including annotations for every detected heart beat and the entire ECG signal are transmitted via cellular telephony network to a remote server accessible by a Monitoring Center for reviewing by trained medical staff.

The patient worn transmitter streams via Bluetooth link the ECG signal to a Windows Mobile or Android OS operated PDA (Personal Digital Assistant) device with mobile phone capabilities. The PDA runs Medicalgorithmics proprietary software which produces QRS annotations and manages the data transmission. The PDA device transmits and stores the entire ECG on its storage card.

5. Indications for Use and contradictions

The indications for use for the PocketECG v2 monitor are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contradictions:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

6. Technological comparison to predicate devices

To K072558 - *Mobile Cardiovascular Outpatient Telemetry*

- Similarities:
  - The subject device and the predicate device analyze the ECG signal in real time
  - The subject device and the predicate device allow for storing 30 or more days of data
  - The subject device and the predicate device utilize a patient-worn sensor and a monitor that communicate with each other wirelessly
- Differences:
  - The subject device produces and sends beat labels for each QRS complex, while the predicate device transmits ECG strips with more generalized description
  - The subject device transmits the entire ECG signal for each day, while the predicate device sends only preselected ECG strips

To K071130 - *Heartrak Smart AF: Cardiac Event Recorder With Atrial Fibrillation Auto-Capture*

- Similarities:
  - The subject device and the predicate device automatically detect atrial fibrillation episodes
  - The subject device and the predicate device allow for patients to mark symptoms and activate transmission
  - The subject device and the predicate device utilize loop memory
  - The subject device and the predicate device send the ECG signal to remote location from patient's home
- Differences:
  - The subject device allows for storing in its loop memory data exceeding 30 days, while the predicate device stores 15 minutes of data
  - The subject device transmits ECG signal over mobile telephony network using file transfer protocol, while the predicate device sends the ECG signal trans-telephonically

To K050731 - *SEER Light Extend Compact Digital Holter System*

- Similarities:
  - The subject device and the predicate device store the entire ECG signal in memory
  - The subject device and the predicate device enable the use of the entire ECG waveform for calculating beat labels for each QRS complex with morphology classification
  - The subject device and the predicate device allow for accessing and printing the full disclosure ECG waveform
- Differences:

- The subject device transmits the entire ECG waveform to a remote location, while for the predicate device the ECG signal has to be downloaded directly onto a computer
- The subject devices analyzes the ECG signal before transmission and transmits the waveform along with all classification results, while the predicate device is used for downloading the ECG signal only and the analysis is performed using an external computer

7. Referenced standards

The Medicalgorithmics Unified Arrhythmia Diagnostic System, PocketECG v2 meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- IEC 60601-1:1999 "Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995"
- IEC 60601-1-2:2001/A1:2004 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests" Class B
- AAMI/ANSI EC38:2007 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- AAMI / ANSI EC57:1998/(R)2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms

Quality management system - Medical devices is in conformance with the standards: PN-EN ISO 9001:2001 and PN-EN ISO 13485:2005.

8. Substantial Equivalence Conclusion

Medicalgorithmics Unified Arrhythmia Diagnostic System, PocketECG v2 is safe, effective and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing. The subject device is composed of off-the-shelf, certified devices and components fully complying with the US safety and EMC standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 16 2012

Medicalgorithmics LLC.
c/o Mr. Martin Jasinski
245 West 107th street, Suite 11A
New York, NY 10025

Re: K112921
Trade Name: PocketECG v2 – Medicalgorithmics unified arrhythmia diagnostic system
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector Alarm
Regulatory Class: Class II (two)
Product Codes: DSI
Dated: May 11, 2012
Received: May 11, 2012

Dear Mr. Jasinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112921 Device Name: PocketECG -v2 - Medicalgorithmics Unified Arrhythmia Diagnostic System

Indications For Use:

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1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea(shortness of breath)
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112921

4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
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Contradictions:

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